

## PATENT COOPERATION TREATY

PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY


(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 13 DEC 2005

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Applicant's or agent's file reference PTD/JPS/2693PC	<b>FOR FURTHER ACTION</b> See Form PCT/PEA/416	
International application No. PCT/GB2004/004564	International filing date (day/month/year) 28.10.2004	Priority date (day/month/year) 28.10.2003
International Patent Classification (IPC) or national classification and IPC A61M1/00, A61M3/02, A61M27/00, A61F13/00, A61F7/00		
Applicant SMITH & NEPHEW PLC ET AL.		
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>		
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input checked="" type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>		
Date of submission of the demand  21.04.2005	Date of completion of this report  13.12.2005	
Name and mailing address of the International preliminary examining authority:   European Patent Office - P.B. 5818 Patentaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer  Lakkis, A  Telephone No. +31 70 340-4136	



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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

**Description, Pages**

1-92 as originally filed

**Claims, Numbers**

1-10 as originally filed

**Drawings, Sheets**

1/8-8/8 as originally filed

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing (*specify*):
- ☐ any table(s) related to sequence listing (*specify*):

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:
- ☐ the entire international application,
  - ☒ claims Nos. 10
- because:
- ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):
  - ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
  - ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
  - ☒ no international search report has been established for the said claims Nos. 10
  - ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
    - the written form ☐ has not been furnished
    - ☐ does not comply with the standard
    - the computer readable form ☐ has not been furnished
    - ☐ does not comply with the standard
  - ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
  - ☐ See separate sheet for further details

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	6-8
	No: Claims	1-5,9
Inventive step (IS)	Yes: Claims	
	No: Claims	1-9
Industrial applicability (IA)	Yes: Claims	1-9
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

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**Box No. VI Certain documents cited**

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1. Certain published documents (Rule 70.10)

and /or

2. Non-written disclosures (Rule 70.9)

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

**Re Item III**

Rules 39.1(iv) and 67.1(iv) PCT - Method for treatment of the human or animal body by therapy

**Re Item V**

The following documents are referred to in this communication:

D1 : WO 84/01904 A1 (SWANBECK, GUNNAR) 24 May 1984 (1984-05-24)

D2 : WO 02/092783 A (CHILDREN'S MEDICAL CENTER CORPORATION) 21 November 2002 (2002-11-21)

D3 : DE 40 12 232 A1 (GROSS, FRANZ JOSEF, 5419 LINKENBACH, DE) 17 October 1991 (1991-10-17)

**INDEPENDENT CLAIM 1**

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT. Document D1 (page 2, last paragraph-page 4, 2nd paragraph, figure 1) discloses (the references in parentheses applying to this document) all the features of claim 1:

An apparatus for irrigating, supplying thermal energy to and cleansing wounds, comprising a fluid flow path comprising a conformable dressing (10) having a backing layer, at least one inlet (11) and one outlet (12) pipe, a means for fluid cleansing (14), a fluid reservoir (15), a device for moving fluid (13), means for supplying thermal energy to the fluid in the wound ("thermostatically regulated water bath", page 4, 1st paragraph), such that fluid may be supplied to fill the flow path and recirculated.

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**INDEPENDENT CLAIM 9**

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 9 is not new in the sense of Article 33(2) PCT. Document D2 (paragraph 62, figures 8B and 9) discloses (the references in parentheses applying to this document) all the features of claim 9:

A conformable dressing (10) (suitable) for use in an apparatus according to claim 1, comprising a backing layer (115), at least one inlet (145) and one outlet (150) pipe the point at which each inlet and outlet pipe passes through and/or under the wound-facing face forming a relatively fluid-tight seal or closure.

Note that D1 (figure 1) and D3 (figure 1) also disclose all technical features of claim 9.

**DEPENDENT CLAIMS 2-8**

Dependent claims 2-8 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step (Article 33(2) and (3) PCT). See the documents and passages cited in the search report.

**Re Item VI**

**Certain documents cited**

The priority documents pertaining to the present application were not available at the time of establishing this opinion. Hence, it is based on the assumption that all claims enjoy priority rights from the filing date of the priority document. If it later turns out that this is not correct, document WO2004/037334 could become relevant.

**Re Item VIII**

Clarity issues (Article 6 PCT):

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Claim 1 contains several optional features which have no limiting effect on the scope of the claim.

Claim 5 contains a disclaimer ("without the circulating fluid coming into... contact...") which renders it unclear.

Claims 7 and 8 cannot depend on claim 3 but rather on claims 5 or 6, since no "other fluid" is defined in claim 3.

Description, page 78, line 30-page 79, line 8 and also page 82, line 31-page 83, line 4: the reference signs do not appear on the drawings.

Description, page 79, lines 20 and 23: double use of reference sign 77.